General

Guideline Title

Prasugrel with percutaneous coronary intervention for treating acute coronary syndromes (review of technology appraisal guidance 182).

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Prasugrel with percutaneous coronary intervention for treating acute coronary syndromes (review of technology appraisal guidance 182). London (UK): National Institute for Health and Care Excellence (NICE); 2014 Jul. 60 p. (Technology appraisal guidance; no. 317).

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: National Institute for Health and Clinical Excellence (NICE). Prasugrel for the treatment of acute coronary syndromes with percutaneous coronary intervention. London (UK): National Institute for Health and Clinical Excellence (NICE); 2009 Oct. 32 p. (Technology appraisal guidance; no. 182).

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Prasugrel 10 mg in combination with aspirin is recommended as an option within its marketing authorisation, that is, for preventing atherothrombotic events in adults with acute coronary syndrome (unstable angina [UA], non-ST segment elevation myocardial infarction [NSTEMI] or ST segment elevation myocardial infarction [STEMI]) having primary or delayed percutaneous coronary intervention.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Acute coronary syndromes:

- Unstable angina (UA)
- ST-segment-elevation myocardial infarction (STEMI)
- Non-ST-segment-elevation myocardial infarction (NSTEMI)

Guideline Category

Assessment of Therapeutic Effectiveness

Treatment

Clinical Specialty

Cardiology

Critical Care

Internal Medicine

Preventive Medicine

Intended Users

Advanced Practice Nurses

Hospitals

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To evaluate the clinical effectiveness and cost-effectiveness of prasugrel for the treatment of acute coronary syndromes with percutaneous coronary intervention

Target Population

Patients with acute coronary syndrome (unstable angina [UA], non-ST-segment-elevation myocardial infarction [NSTEMI] or ST-segment-elevation myocardial infarction [STEMI]) undergoing primary or delayed percutaneous coronary intervention

Interventions and Practices Considered

Prasugrel in combination with aspirin

Major Outcomes Considered

- Clinical effectiveness
    - Nonfatal and fatal cardiovascular events
    - Mortality (from any cause)
    - Atherothrombotic events

    - Incidence of revascularisation procedures
    - Adverse effects of treatment (including bleeding events)
    - Health-related quality of life
- Cost-effectiveness

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an Assessment report. The Assessment report for this technology appraisal was prepared by the Liverpool Reviews and Implementation Group (LRiG) (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Methods for Reviewing Effectiveness

In addition to searching the manufacturer's submission (MS) for relevant references, the following databases were searched for studies of prasugrel:

- EMBASE (Ovid) 1974 to 2013 June 18
- Medline (Ovid) 1946 to 2013 June Week 1
- The Cochrane Library to 2013 June
- PUBMED 2013 January 2010 to 2013 April 28

The results were entered into an EndNote X5 (Thomas Reuters, CA, USA) library and the references were de-duplicated. Full details of the search strategies used are presented in Appendix 1 in the Assessment report.

Inclusion and Exclusion Criteria

Two reviewers independently screened all titles and abstracts identified via searching and obtained full paper manuscripts that were considered relevant by either reviewer (Stage 1). The relevance of each study was assessed according to the criteria set out below (Stage 2). Studies that did not meet the criteria were excluded and their bibliographic details were listed alongside reasons for their exclusion. Any discrepancies were resolved by consensus and, where necessary, a third reviewer was consulted.

Study Design

Only randomised controlled trials (RCTs) were included in the assessment of clinical effectiveness.

Interventions and Comparators

The effectiveness of prasugrel within its licensed indication was assessed. Studies that compared prasugrel with clopidogrel or ticagrelor were considered for inclusion in the review.

Patient Populations

Patients with acute coronary syndromes who were to be treated with primary or delayed percutaneous coronary intervention comprised the relevant population.

Outcomes

Data on any of the following outcomes were included in the assessment of clinical effectiveness: nonfatal and fatal cardiovascular (CV) events, mortality from any cause, atherothrombotic events, incidence of revascularisation procedures, adverse effects of treatment (including bleeding events) and health-related quality of life (HRQoL).

Assessment of Cost-effectiveness

Systematic Review of Existing Cost-effectiveness Evidence

Search Strategy

This review is an update of an existing review; however, searching was not date limited. In addition to searching the MS for relevant references, the following databases were searched for economic evaluations of prasugrel:

- Ovid MEDLINE® (1946 to August Week 3 2013)
- Ovid MEDLINE® In-Process & Other Non-Indexed Citations (searched August 30, 2013)
- National Health Service Economic Evaluation Database (NHS EED) (searched August 30, 2013)
- EMBASE (1974 to 2013 August 30)

The results were entered into an ENDNOTE X5 library (Thomas Reuters, CA, USA) and the references were de-duplicated electronically. Full details of the search strategy are presented in Appendix 1 in the Assessment report.

Inclusion and Exclusion Criteria

At Stage 1, two reviewers independently screened all titles and abstracts. Full paper manuscripts of any titles and abstracts that were considered relevant by either reviewer were obtained where possible. At Stage 2, the relevance of each study was assessed according to the criteria set out in third reviewer was consulted.

	Inclusion Criteria	**Exclusion Criteria**
Intervention or comparator	Prasugrel	
Study design	Full economic evaluation	Methodological paper, letter*, abstract**
Perspective	UK or European perspective	Non-European perspective
Source of publication	Unrelated to previous appraisal	Related to previous appraisal (e.g., NICE/Evidence Review Group [ERG]/Manufacturer)

*Letters were included if they were related to a study already included in the review.

**Abstracts were judged for inclusion at the very end of the inclusion process in order to ascertain whether sufficient information was available for the abstract to be included in the review.

Number of Source Documents

Clinical Effectiveness

A total of 1940 titles and abstracts were screened for inclusion in the review of clinical effectiveness evidence. One relevant randomised controlled trial (TRITON-TIMI 38) was included.

Cost-effectiveness

After de-duplication of 1449 references, a total of 1230 titles and abstracts were screened for inclusion at Stage 1. Of these 1230 references, 1117 were immediately excluded because they did not include prasugrel as an intervention or a comparator. At Stage 2, inclusion criteria were applied to 113 references. During Stage 2, 98 references were excluded leaving a possible 15 references available for potential inclusion. Of the 15 potentially eligible references, none of the papers met the full inclusion criteria that were set by the Assessment Group. The manufacturer of prasugrel submitted an economic model.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an Assessment report. The Assessment report for this technology appraisal was prepared by the Liverpool Reviews and Implementation Group (LRiG) (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Data Extraction Strategy

Data relating to both study design and quality were extracted by two reviewers into an Excel spreadsheet. The two reviewers cross-checked each other's data extraction and where multiple publications of the same study were identified, data were extracted and reported as a single study.

Quality Assessment Strategy

The quality of the clinical effectiveness studies was assessed independently by two reviewers according to the Centre for Reviews and Dissemination at York University's suggested criteria. All relevant information is tabulated and summarised within the text of the report. Full details and results of the quality assessment strategy for clinical-effectiveness studies are reported in Appendix 2 of the Assessment report.

Methods of Data Synthesis

The results of the clinical data extraction and clinical study quality assessment are summarised in structured tables and as a narrative description. An indirect treatment comparison of prasugrel with ticagrelor was planned.

Refer to Section 5 of the Assessment report for more information on clinical effectiveness.

Assessment of Cost-effectiveness

Data Extraction and Quality Assessment Strategy

In the Assessment Group's (AG's) review protocol, data relating to both study design and quality were planned to be extracted by two reviewers into an Excel spreadsheet (Excel software, Henderson, NV, USA). It was also planned that all economic evaluations identified for inclusion in the review would be quality assessed according to the Drummond et al 10-point checklist. However, no studies were identified for inclusion in the AG's review.

Overview of Manufacturer's Submitted Model

Refer to Table 16 (NICE reference case checklist) in the Assessment Report for an overview of the manufacturer's submitted model.

In summary, the manufacturers have submitted the same economic model that they previously presented during the original appraisal of prasugrel for the treatment of acute coronary syndromes with percutaneous coronary intervention (TA182). However, some aspects of the submitted model have been updated in light of feedback generated during the original appraisal of prasugrel (TA182). These revised aspects are:

- Use of sensitivity analysis encompassing the entire population as opposed to a 'typical' patient profile
- Removal of the functionality which allowed the user to choose to model 15 months of treatment (as the licence is only for 12 months)
- Conduct of scenario analysis using the Evidence Review Group's suggestions for utility values, amended long-term relative risk of mortality

and reduced incidence of nonfatal myocardial infarction
- Use of the generic (reduced) price of clopidogrel
- Updated costs

The model was developed with the principle of simulating the TRITON-TIMI 38 trial outcomes as closely as possible. There are two main phases to the model: the active treatment phase, which spans the duration of the clinical trial, and the post-treatment phase, which extrapolates outcomes and costs beyond events that took place during the treatment phase, up until death or lifetime horizon (base case 40 years). Within the trial period, there is an opening 3 day period, modelled using a decision tree, followed by 12 cycles, each of 1 month, up to 12 months. The transitions were time dependent. Long-term mortality was based on adjustment of population life tables to reflect prognostic implications of the events modelled over the short term. The model also permits some costs to accumulate after the end of the trial period.

Refer to Section 6 of the Assessment Report for additional description of the manufacturer's model.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Care Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE Web site. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who Is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

Summary of Appraisal Committee's Key Conclusions on the Evidence for Cost-effectiveness

Availability and Nature of Evidence

The manufacturer submitted an economic model similar to the model described in the National Institute for Health and Care Excellence (NICE) technology appraisal guidance 182.

The Assessment Group developed a 2-phase economic model: a short-term statistical model of the data from the TRITON-TIMI 38 trial and a long-term model projecting outcomes and costs at the end of the first phase up to a maximum of 40 years.

Uncertainties Around and Plausibility of Assumptions and Inputs in the Economic Model

The Committee heard from the Assessment Group that extrapolating the data to 5 years would provide a much more certain estimate of the incremental cost-effectiveness ratios (ICERs) than extrapolating the data to 40 years. The Committee agreed that, although the extrapolation of short-term clinical data over longer time horizons could only increase overall uncertainty, it is necessary in economic modelling and that long time horizons are generally preferable. The Committee concluded that the 40-year time horizon was the most appropriate for decision-making while acknowledging that there will be some uncertainty as a result of the extrapolation of data over the longer time horizon.

The Committee noted that neither the manufacturer nor the Assessment Group had included ticagrelor in their respective models.

Incorporation of Health-related Quality-of-Life Benefits and Utility Values. Have Any Potential Significant and Substantial Health-related Benefits Been Identified That Were Not Included in the Economic Model, and How Have They Been Considered?

Not applicable as the Committee had no concerns about the health-related quality of life data used in either the manufacturer's or the Assessment Group's economic model.

Are There Specific Groups of People for Whom the Technology Is Particularly Cost Effective?

The ICERs for all 4 of the subgroups (ST-segment-elevation myocardial infarction [STEMI] with diabetes, STEMI without diabetes, unstable angina or non-ST-segment-elevation myocardial infarction [NSTEMI] with diabetes, unstable angina and NSTEMI without diabetes) were lower than £20,000 per quality-adjusted life year (QALY) gained. For patients with unstable angina or NSTEMI and diabetes, prasugrel dominated (that is, it was more effective and less costly than) clopidogrel.

What Are the Key Drivers of Cost-effectiveness?

The Committee noted that the estimated QALY gains for prasugrel over the 40-year time horizon for the STEMI without diabetes and the unstable angina or NSTEMI without diabetes subgroups were small (0.084 and 0.053, respectively) and that the difference in costs between prasugrel and clopidogrel treatment was also small (£555 and £248, respectively). It accepted that as a result, the cost effectiveness of prasugrel was highly sensitive to changes in key model assumptions. Therefore, the Committee considered the main driver of cost-effectiveness was which time horizon was considered to be most appropriate for decision-making.

Most Likely Cost-effectiveness Estimate (Given as an ICER)

The Committee concluded that the most plausible ICERs for 3 of the 4 subgroups were: £1600 per QALY gained for the STEMI with diabetes group, £6600 per QALY gained for the STEMI without diabetes group, and £4700 per QALY gained for the unstable angina or NSTEMI without diabetes group. In the 4th subgroup (unstable angina or NSTEMI with diabetes), prasugrel dominated (that is, it was less costly and more effective than) clopidogrel.

How Has the New Cost-effectiveness Evidence That Has Emerged Since the Original Appraisal (TA182) Influenced the Current Recommendations?

The new cost-effectiveness evidence has not influenced the recommendations. There are differences in the cost-effectiveness results submitted during the original appraisal of prasugrel and in the current appraisal which are a result of the different economic models used. In particular, in the current appraisal both the manufacturer and the Assessment Group used the whole licensed population in their models, rather than the typical/median patient profile used in the model for the original appraisal. Also, in the current appraisal the Assessment Group used data from the CAPRIE trial in its long-term model rather than data from TRITON-TIMI 38.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination:

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

The Appraisal Committee considered clinical and cost-effectiveness evidence submitted by the manufacturer of prasugrel and a review of this submission by the Assessment Group. Clinical evidence in the manufacturer's submission was taken from a randomised double-blind trial. Cost-effectiveness evidence was based on an economic model.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of prasugrel for the treatment of acute coronary syndromes with percutaneous coronary intervention

Potential Harms

- The Committee was aware that prasugrel increased the chance of (potentially fatal) bleeding compared with clopidogrel.
- The summary of product characteristics lists the following adverse reactions for prasugrel: increased bleeding risk, hypersensitivity reactions including angioedema, and thrombotic thrombocytopenic purpura.

For full details of adverse reactions, see the summary of product characteristics.

Contraindications

Contraindications

- A history of stroke or transient ischaemic attack is listed as a contraindication in the summary of product characteristics for prasugrel.
- According to the summary of product characteristics, the use of prasugrel in people 75 years or older is generally not recommended. However, if treatment is deemed necessary a reduced maintenance dose of 5 mg should be prescribed. For people who weigh less than 60

kg, the summary of product characteristics states that the 10 mg maintenance dose is not recommended and the 5 mg maintenance dose should be used.

For full details of contraindications, see the summary of product characteristics.

Qualifying Statements

Qualifying Statements

- This guidance represents the views of the National Institute for Health and Care Excellence (NICE) and was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Implementation of the Guideline

Description of Implementation Strategy

- Section 7(6) of the National Institute for Health and Care Excellence (NICE) (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires clinical commissioning groups, National Health Service (NHS) England and, with respect to their public health functions, local authorities to comply with the recommendations in this appraisal within 3 months of its date of publication.
- When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraph above. This means that, if a person has acute coronary syndromes and the doctor responsible for their care thinks that prasugrel is the right treatment, it should be available for use, in line with NICE's recommendations.
- NICE has developed a costing statement (see also the "Availability of Companion Documents" field) explaining the resource impact of this guidance, to help organisations put this guidance into practice.

Implementation Tools

Mobile Device Resources

Patient Resources

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Prasugrel with percutaneous coronary intervention for treating acute coronary syndromes (review of technology appraisal guidance 182). London (UK): National Institute for Health and Care Excellence (NICE); 2014 Jul. 60 p. (Technology appraisal guidance; no. 317).

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2009 Oct (revised 2014 Jul)

Guideline Developer(s)

National Institute for Health and Care Excellence (NICE) - National Government Agency [Non-U.S.]

Source(s) of Funding

National Institute for Health and Care Excellence (NICE)

Guideline Committee

Appraisal Committee

Composition of Group That Authored the Guideline

Committee Members: Professor Andrew Stevens (*Chair of Appraisal Committee C*), Professor of Public Health, University of Birmingham; Professor Eugene Milne (*Vice Chair of Appraisal Committee C*), Director of Public Health, City of Newcastle upon Tyne; Professor Kathryn Abel, Director of Centre for Women's Mental Health, University of Manchester; Dr David Black, Medical Director, NHS South Yorkshire and Bassetlaw; David Chandler, Lay Member; Gail Coster, Advanced Practice Sonographer, Mid Yorkshire Hospitals NHS Trust; Professor Peter Crome, Honorary Professor, Dept of Primary Care and Population Health, University College London; Professor Rachel A Elliott, Lord Trent Professor of Medicines and Health, University of Nottingham; Dr Greg Fell, Consultant in Public Health, Bradford Metropolitan Borough Council; Dr Alan Haycox, Reader in Health Economics, University of Liverpool Management School; Dr Janice Kohler, Formerly Senior lecturer and consultant in paediatric oncology, Southampton University Hospitals Trust; Emily Lam, Lay Member; Dr Nigel Langford, Consultant in Clinical Pharmacology and Therapeutics and Acute Physician, Leicester Royal Infirmary; Dr Allyson Lipp, Principal Lecturer, University of South Wales; Dr Claire McKenna, Research Fellow in Health Economics, University of York; Professor Gary McVeigh, Professor of Cardiovascular Medicine,

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Financial Disclosures/Conflicts of Interest

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: National Institute for Health and Clinical Excellence (NICE). Prasugrel for the treatment of acute coronary syndromes with percutaneous coronary intervention. London (UK): National Institute for Health and Clinical Excellence (NICE); 2009 Oct. 32 p. (Technology appraisal guidance; no. 182).

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site .

Availability of Companion Documents

The following are available:

- Prasugrel with percutaneous coronary intervention for treating acute coronary syndromes (review of technology appraisal guidance 182). Costing statement. London (UK): National Institute for Health and Care Excellence (NICE); 2014 Jul. (Technology appraisal guidance; no. 317). Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site .
- Greenhalgh J, Bagust A, Boland A, Dwan K, Beale S, Fleeman N, McEntee J, Dundar Y, Richardson M, Fisher M. Prasugrel with percutaneous coronary intervention for treating acute coronary syndromes (review of TA182). Liverpool (UK): The Liverpool Reviews and Implementation Group, The University of Liverpool; 2013 Dec. 150 p. Electronic copies: Available from the NICE Web site .

Patient Resources

The following is available:

- Prasugrel with percutaneous coronary intervention for treating acute coronary syndromes (review of technology appraisal guidance 182). Information for the public. London (UK): National Institute for Health and Care Excellence (NICE); 2014 Jul. (Technology appraisal guidance; no. 317). Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site . Also available for download as a Kindle or EPUB ebook from the NICE Web site .

NGC Status

This NGC summary was completed by ECRI Institute on September 7, 2010. This NGC summary was updated by ECRI Institute on September 10, 2014.

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